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In re Application of
Q. Liu et al
Serial No. : 09/989,994
Filed : November 20, 2001
Attorney Dkt No. : 8325-0011.20

Decision on Petition

This letter is in response to the Petition under 37 C.F.R. 1.144 & 1.181, filed on 22 July 2004, to request review and withdrawal of the final restriction requirement. The delay in acting on this petition was due, in part, to the filing of the petition decision within the body of a response to an Office action, which delayed routing of the petition to the deciding official. Petitions should be filed as separate correspondence.

BACKGROUND

A review of the file history shows that the application was filed on November 20, 2001 with 49 claims.

On December 22, 2003, the Office required the restriction of the 49 claims to one of greater then 90 different inventions under 35 U.S.C. 121. The greater then 90 different inventions were divided into two groups, half of the inventions were drawn to specific zinc-finger polypeptides comprising a first (F1), a second (F2) and a third (F3) zinc finger, class 530, subclass 300, and half of the inventions were drawn to a specific polynucleotide encoding a zinc-finger polypeptides comprising a first (F1), a second (F2) and a third (F3) zinc finger class 536, subclass 23.1. Applicants were instructed to choose either a polypeptide group or a polynucleotide group and choose one sequence for F1, one sequence for F2, and one sequence for F3 from the table listed on page 2 of the restriction requirement or one polynucleotide sequence which encodes the peptide sequence of F1, F2, and F3. The table on page 2 of the restriction requirement lists the sequences recited in claim 1. It was further pointed out to applicant that it would be understood that all three F1, F2, and F3 sequences or their encoding polynucleotides will be found or occur in the same polypeptide or polynucleotide.

On January 26, 2004, applicants elected with traverse a polypeptide comprising the combination of DRSNLTR for F1; TSGHLSR for F2; and RSDHLSR for F3.

On March 18, 2004, the examiner prepared a first action on the merits which acknowledged the election with traverse of a zinc finger protein comprising F1 sequence DRSNLTR, F2 sequence TSGHLSR and F3 sequence RSDHLSR. The examiner found

the traversal non-persuasive and further rejected those claims drawn to the elected subject matter under 35 U.S.C. 112 first and second paragraphs, 35 U.S.C. 102 and double patenting.

On July 22, 2004, in response to the first office action on the merits, applicants filed the instant petition requesting review and withdrawal of the final restriction requirement. Within the same paper, applicants submitted their response to the Office action. It is noted that petitions should be submitted as a separate paper and should not be combined with other correspondence.

DISCUSSION

The application, file history and petition under 37 C.F.R. 1.144 & 1.181, to request review and withdrawal of the final restriction requirement has been considered.

Applicants describe their invention as the discovery of the position dependence of zinc finger sequences, however, the claims are not directed to a method of discovery, methods of production or even to the set of zinc finger trimers proteins so discovered. The claims are directed to individual zinc finger trimers and reads upon proteins which may have been produced via applicant's approach or produced by other techniques. For product claims, it is the structure and function of the product, not the method by which the product was produced (or discovered) that imparts patentability.

Applicants submit that the restriction requirement is unclear because it states that there are 45 amino acid sequences claimed, when only 43 are claimed. Applicants are correct that 43 and not 45 possible combinations of F1, F2 and F3 recited in claim 1.

Applicants further submit that the restriction requirement was unclear by requiring election of one of fifteen groups. Applicants note the ramifications of such a restriction requirement on this and related applications with respect to double patenting issues and argue that such a requirement would prevent applicants from claiming their invention. This argument is not persuasive for three reasons.

(1) Nowhere does the previous restriction requirement require that applicants elect one of fifteen groups. There is no mention of the number fifteen in the restriction requirement. The only fifteen that can be found in referenced communications is that reference made by applicants in their argument. The table listed on page 2 of the restriction requirement reflects the sequences in claim 1 and has fifteen rows corresponding to fifteen different target sites which are combined in groups of three for 45 (or, leaving out two, 43) inventions.

(2) Moreover, in the election and traversal, applicants did not argue that only 15 groups were set forth in the restriction requirement.

(3) In fact, applicants must have comprehended what was required because they elected a trimer of zinc finger proteins outside of the alleged 15 groups, in which each zinc finger protein binds to the three different codons GAC, GGT and GGG. For these reasons, the original restriction requirement is considered to be clear and complete.

Turning now to the argument that the restriction should have been an election of species per 803.02, MPEP 803.02 states:

> If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in In re Weber, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. In re Harnish, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Applicants submit that all of the claimed proteins share the common utility of sequence-specific DNA-binding and that each of these proteins possess a substantial structural feature, namely a set of three zinc fingers, that is disclosed as being essential to that utility. Applicants' complete argument is acknowledged, however, found non-persuasive on the basis that the utility of the claimed proteins is not that they bind to DNA in a sequence-specific manner, but rather that they bind to a specific sequence of DNA, such as "GACGGTGGG", as elected by applicants. The substantial structural feature disclosed as being essential to that utility is the specific amino acid sequence of the claimed zinc finger polypeptides. This substantial structural feature which is essential to the specific utility of each of the specific zinc finger proteins is specific to each specific utility or sequence and not shared by the other zinc finger proteins listed in the claim. The zinc finger trimers cannot be substituted one for another to achieve the same effect. Thus, as the zinc finger proteins recited in claim 1 of the instant application do not share a common utility nor do they share any substantial structural feature, let alone any substantial feature disclosed as being essential to that utility, it is thus proper for the Office to set forth a restriction requirement within a claim. For these reasons, the proteins recited in the alternative in claim 1 do not qualify for Markush-type election of species practice per 803.02.

Even if one was to concede that the zinc finger proteins included within claim 1 were a proper Markush group, sharing a common utility, and sharing a substantial structural feature, disclosed as being essential to that utility, claim 1 includes approximately 15^3 different zinc finger proteins, a number of which is not sufficiently few in number or so closely related that a search of the entire claim could be made without serious burden.

Claim 1 does not recite a groups of compounds having "unity of invention." Claim 1 recites proteins listed in the alternative. Claim 1 could be written as a series of dependent claims that capture the full scope of the claim, without loss or overlap of

scope. No linking claims exist. Thus restriction between the zinc finger proteins listed in claim 1 is proper.

Applicants traverse the restriction requirement on the basis that its maintenance would present undue burdens to both applicants and the office, it would require the filing of either 29 or 89 additional applications. This is not persuasive on the basis that the number of patent applications required to cover applicants claimed number of different independent and distinct inventions is not pertinent to the propriety of a restriction requirement.

Applicants further argue that restriction between proteins and nucleic acids is supported by throwaway utilities not based on sound reasoning applicable to the facts of the currently pending case. Applicants submit that the Examiner's assertions that the protein could be made by a materially different process (synthesis or purification from a natural source) and that the polynucleotide encoding a non-naturally occurring protein could not serve as a hybridization probe.

Applicants' complete argument regarding the restriction requirement between the proteins and polynucleotides is acknowledged but deemed to be not persuasive in view of the following reasons. Applicants correctly note that a restriction requirement may have ramifications on this and related applications with respect to double patenting issues.

Applicants' attention is directed to allowed application number 10/006,069, commonly assigned to the same assignee as with the instant application and also by the inventor Qiang Liu. Application number 10/006,069 contains allowed claim 99 which is directed to a purified nucleic acid encoding a polypeptide comprising a zinc finger protein that comprises SEQ ID Nos 55, 247 and 68. It is noted that SEQ ID Nos 55, 247 and 68 of 10/006,069 are identical to the elected sequences DRSNLTR TSGHLSR and RSDHLSR of 09/989,994. It is noted that the restriction requirements in both applications are comparable with respect to separation of the nucleic acid and protein inventions.

Because the allowed claims in the above referenced co-assigned application are to the purified nucleic acid encoding the elected zinc finger protein, now pending in the instant application, the rejoining of nucleic acid claims to the elected polypeptide group would conflict with the restriction requirement set forth in 10/006,069, which also separates the nucleic acid and protein inventions and which applicants have accepted without petition. The Office will not issue two patents containing claims to the same invention. Moreover, the Office cannot make a double patenting rejection among inventions which were claimed in separate applications as a result of a restriction requirement.

37 CFR 1.78 states:

(b) Where two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application.

It appears that the requests made in this petition are counter to the requirement of 37 CFR 1.78(b). Had the petition been granted, it would result in the same invention being claimed in two applications without a possibility of the Office addressing the double patenting issues. The burden is upon applicant to maintain a clear line of distinction between inventions in different applications. Thus maintenance of the restriction requirement between proteins and nucleic acids in this particular application, is proper and consistent in view of the restriction requirement set forth and accepted in the related application.

Finally, applicants assert that their election was improper because the restriction requirement did not provide the choice of RSDNLAR, RSDNLAR and RSDNLTR. This is not correct. The sequences now being proposed are found in table on page 2 of the restriction requirement in F1 column, line 2, F2 column, line 2 and F 3 column, line 2, respectively. Moreover, MPEP 818.01 and 819 states that the election is fixed upon receipt of an office action on the merits and the Office is under no obligation to allow applicants to switch their election. The elected invention has already received an action on the merits. No switch in the elected invention will be permitted.

DECISION

For these reasons, the Petition under 37 C.F.R. 1.144 and 1.181 to request withdraw of the restriction requirement and permit applicants to change their elected invention is **DENIED**.

Any request for consideration must be filed within two (2) months of the mailing date of this decision.

The application will be forwarded to the examiner for consideration of the Office action filed on 22 June 2004 as part of the same paper as the petition.

Should there be any questions regarding this decision, please contact Special Program Examiner Julie Burke, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-1600 or by Official Fax at 703-872-9306.

Bruce Kisliuk
Director, Technology Center 1600.